

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A., INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant.

Civil Action No. 13-cv-1729-SLR

**PLAINTIFF TAKEDA PHARMACEUTICAL U.S.A., INC.'S MEMORANDUM IN  
SUPPORT OF ITS MOTION FOR LEAVE TO FILE AN AMENDED COMPLAINT**

Mary W. Bourke (#2356)  
WOMBLE CARLYLE SANDRIDGE & RICE, LLP  
222 Delaware Avenue, Suite 1501  
Wilmington, DE 19801  
mbourke@wCSR.com  
Phone: (302) 252-4333

Of Counsel:

Tryn T. Stimart  
WOMBLE CARLYLE SANDRIDGE & RICE, LLP      *Attorneys for Takeda Pharmaceuticals U.S.A., Inc.*  
8065 Leesburg Pike, 4<sup>th</sup> Floor  
Tysons Corner, VA 22182-2738  
tstimart@wCSR.com

Jeffrey I. Weinberger  
Ted G. Dane  
MUNGER, TOLLES & OLSON LLP  
355 South Grand Avenue  
Thirty-Fifth Floor  
Los Angeles, California 90071-1560  
jeffrey.weinberger@mto.com  
ted.dane@mto.com

Eric K. Chiu  
MUNGER, TOLLES & OLSON LLP  
560 Mission Street  
San Francisco, California 94105-2907  
eric.chiu@mto.com

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Pursuant to Federal Rule of Civil Procedure (“Rule”) 15(a)(2) and District of Delaware Local Rule 15.1, Plaintiff Takeda Pharmaceutical U.S.A., Inc. (“Takeda”) moves for leave to file an Amended Complaint. Takeda has filed this motion in a timely manner and without dilatory motive, and allowing the requested amendment will not unduly prejudice Amneal. Accordingly, Takeda respectfully submits that the Court should grant its motion.

Takeda’s current claims against Amneal allege that Amneal’s manufacture and/or sale of a generic version of Colcrys® would directly infringe and induce infringement of Takeda’s patents directed to using colchicine to treat Familial Mediterranean Fever (“FMF”). Takeda now seeks to add a claim for declaratory judgment that such manufacturing and sales activity will contribute to the infringement of Takeda’s patents directed to methods for using colchicine to treat and prevent gout flares (the “gout patents”). Although Amneal abandoned its request for FDA approval to sell its generic product for gout-related indications, the evidence strongly indicates that Amneal will contribute to physicians’ and patients’ infringement of the gout patents. The overwhelming majority of prescriptions written for Colcrys® in the United States are for the prevention and treatment of gout flares. Publicly available information shows that far less than 1% of prescriptions in the United States written for Colcrys® are for treating FMF—a rare disease in the United States, defined by the National Institute of Health as one with less than 200,000 affected individuals.<sup>1</sup> Amneal’s efforts to seek FDA approval for an insubstantial market (FMF) while at the same time ignoring a much larger and more profitable market (gout)

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<sup>1</sup> See 42 U.S.C. § 2871a-1(c); Declaration of Mary W. Bourke, Esq. (hereinafter, “Bourke Declaration”) ¶ 3, Ex. A [NIH Office of Rare Disease Website], filed concurrently.) Although the exact number of FMF patients in the United States is unknown, national prescription data indicates that the number of FMF patients in the United States is no more than a few thousand individuals. (See Declaration of Nirav Gandhi (hereinafter, “Gandhi Decl.”) ¶¶ 3-4, Ex. A-B [Summary of Encuity and IMS/NDTI prescribing data]; Bourke Declaration ¶¶ 9-12, Exs. G-J [Summary of Encuity and IMS/NDTI prescribing data], filed concurrently.)

that relies on the exact same drug (Colcrys®) is implausible and belie rational economic principles.

**I. NATURE AND STAGE OF THE PROCEEDINGS**

This is a Hatch-Waxman patent infringement case. Amneal filed an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration, seeking approval to commercially market generic versions of the drug product Colcrys® (colchicine, USP) before the expiration of the FMF Patents, which cover the Colcrys® product. On October 21, 2013, Plaintiff accordingly sued Amneal for infringement of United States Patent Nos.

7,906,519; 7,935,731; 7,964,648; 8,093,297; 8,093,298 (collectively the “FMF Patents”). (D.I.

1.) This case is currently schedule for trial beginning August 3, 2015. (D.I. 14.)

**II. BACKGROUND**

Colchicine is a plant extract that helps to decrease the inflammatory response associated with gout.<sup>2</sup> Colchicine is prescribed to treat and prevent gout flares. In addition to its therapeutic benefits, colchicine has serious side effects, including nausea, vomiting, and diarrhea. Colchicine is a low therapeutic index drug with a narrow margin for an effective dose; without proper oversight, colchicine concentrations in the body can build up, causing severe side effects, including death. Co-administration of colchicine with certain other drugs can also cause elevated colchicine levels in the body, resulting in dangerous, even fatal, levels. As a result of extensive research, Mutual Pharmaceutical Company (“Mutual”), a former affiliate of Takeda, discovered methods for safely administering colchicine to patients, both alone and concomitantly with other drugs, to avoid these toxic side effects. In 2009, Mutual (now Takeda) became the first and only entity to receive FDA approval to sell colchicine in the United States under the trade name

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<sup>2</sup> Gout is a type of severe arthritis caused by uric acid build-up in the joints. It is typically characterized by “flares” (severe and sudden attacks of pain, redness, inflammation, and tenderness in the joints).

Colcrys®. Because of Takeda's efforts, the FDA approved New Drug Application ("NDA") Nos. 22-351 and 22-353 for the manufacture and sale of single-ingredient oral colchicine for the prevention and treatment of gout flares. Takeda also received FDA approval for NDA No. 22-352 to manufacture and sell single-ingredient oral colchicine for the treatment of Familial Mediterranean Fever. At present, Colcrys® is the only single-ingredient oral colchicine product lawfully available on the U.S. market.

Takeda owns fourteen patents relating to the use of colchicine to treat and prevent gout flares. The patents are listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") in support of patent exclusivity on Colcrys®. These patents are U.S. Patent No. 7,619,004 (the "'004 patent"), U.S. Patent No. 7,601,758 (the "'758 patent"), U.S. Patent No. 7,820,681 (the "'681 patent"), U.S. Patent No. 7,915,269 (the "'269 patent"), U.S. Patent No. 7,964,647 (the "'647 patent"); U.S. Patent No. 7,964,648 (the "'648 patent"), U.S. Patent No. 7,981,938 (the "'938 patent"), U.S. Patent No. 8,093,296 (the "'296 patent"), U.S. Patent No. 8,093,297 (the "'297 patent"), U.S. Patent No. 8,097,655 (the "'655 patent"), U.S. Patent No. 8,415,395 (the "'395 patent"), U.S. Patent No. 8,415,396 (the "'396 patent"), U.S. Patent No. 8,440,721 (the "'721 patent"), and U.S. Patent No. 8,440,722 (the "'722 patent) (collectively, the "gout patents"). The '004, '647, '648, '938, '296, '297, '655, '395, and '396 patents expire in 2028, and the '758, '681, '269, '721, and '722 patents expire in 2029.

In late 2012, Defendant Amneal Pharmaceuticals, LLC ("Amneal"), sought approval of an Abbreviated New Drug Application ("ANDA") for a generic version of Colcrys® specifically indicated for the treatment and prevention of gout flares. At that time Amneal knew of the issued gout patents that Takeda seeks to add to this matter, as evidenced by Amneal's notice

letters to Takeda in conjunction with its original ANDA. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV”), Amneal certified that Takeda’s Orange Book listed gout patents were either invalid or would not be infringed by Amneal’s proposed ANDA product. Shortly thereafter, on March 28, 2013, Takeda filed suit against Amneal in this Court, stating claims for infringement of Takeda’s gout patents under 35 U.S.C. §§ 271(e), and seeking a declaratory judgment that Amneal would indirectly infringe Takeda’s gout patents. (See D.I. 1 [Compl.]; D.I. 60 [3d Am. Compl.] in *Takeda Pharm. U.S.A., Inc. v. Amneal Pharm., LLC*, No. 13-cv-493-SLR.<sup>3</sup>)

On or about August 28, 2013, Takeda received a phone call from Amneal’s litigation counsel informing that Amneal had voluntarily elected to abandon its request for FDA approval with respect to the treatment and prevention of gout flares and that it would be submitting a label amendment for the purpose of limiting its FDA approval solely to the treatment of FMF. Shortly thereafter, Amneal followed through and pursuant to 21 U.S.C. § 355(j)(2)(a)(viii) (a so-called “section viii carve out”), Amneal certified to the FDA that it was no longer seeking FDA approval of generic Colcrys® for the treatment or prevention of gout flares. Amneal also added new Paragraph IV certifications that its proposed ANDA product would not infringe Takeda’s five Orange Book listed patents for the use of colchicine to treat FMF (the “FMF patents”).<sup>4</sup> In response, Takeda filed the present lawsuit focused on Amneal’s infringement under section 271(e)(2) of the FMF patents.

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<sup>3</sup> The Amended Complaint in the stayed case does not assert the ’721 and ’722 patents because, at that time, Takeda had not yet received notice of Paragraph IV Certifications from Amneal with respect to these two later-issued patents.

<sup>4</sup> Two patents, the ’648 and ’297 patents, contain claims directed to both the use of colchicine to treat and prevent gout flares and treat FMF and thus are already patents-in-suit in this case.

Nevertheless, as discussed in detail *infra*, FMF is a rare disease, which the National Institute of Health defines as a disease with fewer than 200,000 patients. *See* 42 U.S.C. § 281a-1(c); Bourke Decl. ¶ 3, Ex. A [NIH Office of Rare Disease Website].) National prescription data for colchicine shows that, on average, about one in six-hundred and twenty-five colchicine prescriptions written in the United States over the past several years has been for the treatment of FMF, making a generic drug directed solely to treating FMF an economically impractical venture. (*See* Bourke Declaration ¶¶ 9-12, Exs. G-J [Summary of Encuity and IMS/NDTI prescribing data].) As explained below, the practical consequence of Amneal's actions is that its proposed generic version of Colcrys® will be sold primarily to the gout market and therefore contribute to the infringement of Takeda's gout patents. Accordingly, Takeda now in good faith seeks leave to amend the complaint to seek a declaratory judgment that Amneal's proposed ANDA product will infringe Takeda's gout patents under 35 U.S.C. § 271(c).

### **III. SUMMARY OF THE ARGUMENT**

1. Federal Rule of Civil Procedure 15(a)(2) allows a court to grant a party's request for leave to amend a pleading, without having to show "good cause," any time prior to the court's deadline for seeking such amendments. Rule 15(a)(2) provides that courts should grant such leave "freely" "when justice so requires."

2. To prevail in opposing Takeda's request, Amneal must show that Takeda's request is either untimely, futile, filed with dilatory motive, or that it will suffer undue prejudice. *Dole v. Arco Chem. Co.*, 921 F.2d 484, 486-87 (3d Cir. 1990).

3. Takeda has sufficiently demonstrated all elements to plead contributory infringement under 35 U.S.C. §271(c) and Takeda's pleading is permissible when the major indication is carved out of the proposed drug label. *Novartis Pharms. Corp. v. Wockhardt USA LLC*, No. 13-1028, 2013 WL 5770539 (D.N.J. Oct. 23, 2013).

4. Takeda's drug Colcrys® is used for the treatment and prevention of gout flares and to treat FMF. Over 8.3 million people suffer from gout; the number of people suffering from FMF is comparatively insubstantial. Takeda filed the instant action based on Amneal's efforts to obtain FDA approval to market and sell generic Colcrys® in the FMF market, which activities would infringe five Takeda patents relating to the administration of colchicine to treat FMF. Takeda has reason to believe, however, that Amneal intends and expects to sell its generic product to treat gout patients, notwithstanding it is not seeking approval for that indication. If Amneal's strategy is successful, Takeda's Colcrys® market will be destroyed and Takeda will suffer irreparable harm.

5. Takeda's request is filed before the deadline for amending pleading in this action and therefore is timely. (D.I. 14.) Takeda has filed its motion to protect its Colcrys® patent rights and therefore its request is not futile and not filed with dilatory motive. Amneal will not suffer prejudice if Takeda's motion is granted as Amneal is familiar with the patents sought to be added, has already provided noninfringement and invalidity positions to those patents, and there is sufficient time before the FDA can approve Amneal's proposed ANDA.

6. Accordingly, Takeda respectfully requests that its motion be granted.

#### **IV. ARGUMENT**

##### **A. Rule 15(a)(2) requires courts to grant leave to amend “freely.”**

Pursuant to Federal Rule of Civil Procedure 15(a)(2), a party may request the court's leave to amend a pleading, without having to show “good cause,” any time prior to the court's deadline for seeking such amendments. Rule 15(a)(2) provides that courts should grant such leave “freely” “when justice so requires.” FED. R. CIV. P. 15(a)(2). Rule 15(a) “embodies a liberal approach to amendment to “ensure[] that a particular claim will be decided on the merits rather than on technicalities.” *Dole*, 921 F.2d at 486-87. A court commits error in denying leave

to amend unless the nonmoving party can show “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of amendment.” *Id.* at 487 (*quoting Foman v. Davis*, 371 U.S. 178, 182 (1962)); *see also Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993).

Here, the Court’s scheduling order requires that all motions to amend the pleadings be filed by August 1, 2014. (D.I. 14.) Accordingly, Takeda’s motion is timely. Thus, Takeda’s motion should be granted unless Amneal establishes: (1) undue delay, bad faith or dilatory motive; (2) undue prejudice by virtue of the amendment; or (3) futility of amendment. *See Dole*, 921 F.2d at 487. None of these grounds exist here.

**B. Takeda brings this Motion in good faith, without any dilatory motive.**

Takeda brings this motion to amend the complaint in good faith and without any dilatory motive. Amneal is fully aware of the substantial number of patents that cover the gout indication. It is also fully aware that treatment of FMF is a very minor and insubstantial use of colchicine. Amneal’s proposal to remove gout indications from its label—submitted in the midst of a lawsuit challenging Amneal’s generic product—effectively removes from Amneal’s ANDA the only substantial and profitable use of a generic colchicine drug product. Accordingly, Takeda submits that Amneal’s strategy is to avoid litigating the fourteen gout patents and attempt to invalidate the smaller number of patents directed to FMF while still intending to capture sales in the gout market which it knows full well will happen due to the prescribing pattern of physicians. (Boomershine Decl.<sup>5</sup> ¶¶ 4, 5, 10-12.)

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<sup>5</sup> The “Boomershine Decl.” is the Declaration of Dr. Chad Boomershine, filed concurrently.

*1. The FMF market in the United States is insignificant.*

The National Institute of Health (“NIH”) categorizes FMF as a “rare disease” in the United States. (See Bourke Decl. ¶ 3, Ex. A [NIH Office of Rare Disease Website].) The Rare Disease Act of 2002, which established the NIH’s Office of Rare Diseases, defines a rare or orphan disease as one typically afflicting fewer than 200,000 individuals in the United States. Pub. L. No. 107-280, 116 Stat. 1988, 1990 (codified at 42 U.S.C. § 287a-1). Orpha.net, a worldwide portal compiling information on rare diseases, also categorizes FMF as a rare disease in the United States, reporting that 1/200-1/1000 persons of non-Ashkenazi Jewish, Turkish, Armenian, and Arab descent are affected by FMF. (See Bourke Decl. ¶ 4, Ex. B [Orpha.net Website].) In contrast, as of 2008, an NIH survey reported that approximately 8.3 million people in the United States suffer from gout.

To further shed light on the size of the FMF market and Amneal’s intentions in submitting its “section viii” carve-out, Takeda obtained prescription data from two providers of national prescription data, Encuity Research and IMS Health. (See Bourke Declaration ¶¶ 9-12, Exs. G-J [Summary of Encuity and IMS/NDTI prescribing data].) The data indicates that, on average, only about 0.16% (or one in every six-hundred and twenty-five) of approximately 9.2 million total colchicine prescriptions in the United States in recent years have been for the treatment of FMF, with the vast majority of prescriptions written for treating and preventing gout flares. In other words, the size of the United States patient market for FMF is very small, and would not by itself justify investment in a generic drug product.

*2. Amneal has resisted discovery regarding its label amendments and plans to sell its product to gout patients.*

Takeda has also diligently sought discovery from Amneal to confirm that its election to carve out gout indications from its ANDA application did *not* indicate an intent to limit sales to

the insubstantial FMF market. For example, Takeda sought documents and things relating to Amneal’s decision to seek approval to market its proposed ANDA product for the treatment of FMF; Amneal’s plans to design its proposed ANDA product; Amneal’s plans to market its proposed ANDA product; and Amneal’s knowledge that its proposed ANDA product will be used for the treatment and prevention of gout flares. (See, e.g., Bourke Decl. ¶ 5, Ex. C [Plaintiff’s First Set of Requests for Production to Amneal Pharmaceuticals, Inc. at Request Nos. 13-16, 32-33, and 35].) Takeda also served Interrogatories asking Amneal to “[s]tate the basis for [its] decision to carve out the gout indications from the Colcrys® label including any financial, marketing, clinical, legal or other factors leading to [its] decision.” (See Bourke Decl. ¶ 6, Ex. D [Plaintiff’s First Set of Interrogatories to Amneal Pharmaceuticals, LLC at Interrogatory No. 1].) Amneal objected to Takeda’s requests and has not yet produced the requested documents or otherwise explained its decision for its carve-out of the gout indications.

Notwithstanding Amneal’s lack of responsiveness, Takeda has a sufficient basis for asserting a claim that Amneal knows that its generic colchicine product will infringe and contribute to infringement of Amneal’s gout patents following FDA approval. Takeda thus seeks to amend the Complaint in good faith and, under the factual circumstances, has done so as timely as possible.

**C. Amneal will not suffer undue prejudice by virtue of Takeda’s amendment.**

Amneal will not suffer undue prejudice by virtue of Takeda’s proposed amendment. Prejudice to the nonmoving party must be “substantial or undue” to be a sufficient basis for the denial of a timely request for leave to amend. *See Cureton v. NCAA*, 252 F.3d 267, 273 (3d Cir. 2001) (citing *Lorenz*, 1 F.3d at 1414). The nonmoving party has the burden to demonstrate prejudice, *Kiser v. Gen’l Elec. Corp.*, 831 F.2d 423, 428 (3d Cir. 1987), and must “demonstrate

that its ability to present its case would be seriously impaired were amendment allowed.” *Dole*, 921 F.2d at 488.

Amneal will not suffer substantial or undue prejudice or serious impairment to its case if required to litigate infringement of the gout patents. When Amneal elected to change its carve-out strategy, Amneal had already articulated noninfringement and invalidity defenses to the twelve patents Takeda seeks to add to this case. Moreover, the parties had completed substantial production of documents and identified claim terms likely needing resolution by the Court. The parties would need simply to resume where discovery had left off at the time of Amneal’s decision to amend its label, which is with deposition discovery of fact witnesses. As noted above, Takeda’s Orphan Drug Exclusivity for the FMF indication does not expire until July 29, 2016, nearly one year after the current trial date. Thus, completely independent of the current patent infringement litigation, the FDA cannot approve Amneal’s generic drug until after Takeda’s regulatory exclusivity expires. Accordingly, if the Court allows the amendment, Takeda’s infringement claims under its gout patents easily can be resolved prior to the earliest date that Amneal would be able to come to market.

While the proposed amendment will not unduly prejudice Amneal, denial of the amendment would prejudice Takeda. If the Court denies the amendment and Amneal succeeds in its noninfringement and validity challenges to the FMF patents, Amneal could launch its generic colchicine product upon expiration of Takeda’s regulatory exclusivity, and begin making significant sales in the gout market. Takeda would thereby be threatened with the very harmful conduct underlying its contributory infringement claim, likely necessitating expedited relief such as an application for a temporary restraining order and/or motion for preliminary injunction. If Takeda is not able to obtain such extraordinary relief, Amneal’s entry into the gout market may

have permanent effects on Takeda's market position, causing it irreparable harm. This entire scenario is mitigated by granting Takeda's instant motion and allowing the parties to litigate all patents protecting Colcrys® together.

**D. Takeda has met the pleading requirements to state a declaratory judgment claim for contributory infringement of its gout patents under 35 U.S.C. § 271(c)**

*1. Takeda has pled each element of a contributory infringement claim.*

“To prove contributory infringement a plaintiff must demonstrate the following: (1) an offer to sell, sale, or imports; (2) a component or material for use in a patented process constituting a material part of the invention; (3) knowledge by the defendant that the component is especially made or especially adapted for use in an infringement of such patents; and (4) the component is not a staple or article suitable for substantial noninfringing use.” *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, No. 99-cv-00274-SLR, 2004 WL 1305849, at \*7 (D. Del. June 9, 2004), *vacated in part on other grounds by* 425 F.3d 1366 (Fed. Cir. 2005); *see also Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010); *Lucent Techs. Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320 (Fed. Cir. 2009).

(a) Amneal will offer to sell a material for a patented method that constitutes a material part of the invention.

Takeda's amended complaint alleges that Amneal will offer to sell colchicine, a material part of its claimed invention, in violation of Takeda's gout patents. Amneal filed the ANDA giving rise to this litigation for the purpose of selling generic Colcrys® in the United States. Upon obtaining FDA approval and the expiration of Takeda's orphan drug exclusivity, Amneal can manufacture and sell its proposed colchicine product in the United States. Amneal's

proposed colchicine product is material – indeed, essential – to Takeda’s patented methods for treating and preventing gout flares with colchicine.

(b) Amneal has knowledge that the component is especially made for an infringing use.

The Supreme Court articulated the knowledge requirement for contributory infringement as: “[A] showing that the alleged contributory infringer both knew that the combination for which his component was especially designed was both patented and infringing.” *Aro Mfg. Co. v. Convertible Top Replacement*, 377 U.S. 476, 488-89 (1964); *see also Bone Care Int’l, L.L.C. v. Roxane Labs., Inc.*, No. 09-cv-0285-GMS, 2012 WL 2126896, at \*30 (D. Del. June 11, 2012) (in reliance on copyright law principles in a patent case, holding that “[i]ntent is presumed in a contributory infringement analysis.” (citing *Metro-Goldwyn-Mayer Studios v. Grokster Ltd.*, 545 U.S. 913, 932 (2005)).

Takeda’s amended complaint alleges that Amneal knew that its proposed colchicine product is especially made for a use that is patented and infringing. Amneal’s original Paragraph IV certifications in the now stayed gout cases serve as clear evidence that Amneal knows the use for which generic Colcrys® is primarily designed—to treat and prevent gout flares—will infringe Takeda’s gout patents. In its notice letters, Amneal listed and described Takeda’s Orange Book gout patents, indicating actual knowledge of each of those patents. In addition, Amneal demonstrated a clear understanding that its proposed colchicine product is designed for the infringing use of preventing and treating gout flares. Amneal stated that its generic product will be “marketed for two of the currently approved indications for Colcrys® tablets, namely the prophylaxis and treatment of acute gout flares” and its proposed label set forth specific recommended doses for both prophylaxis and treatment of gout flares.

(c) There is no substantial non-infringing use.

Takeda's amended complaint further alleges that there is no substantial noninfringing use for Amneal's proposed ANDA product. To state a claim under 35 U.S.C. § 271(c), "a plaintiff must . . . plead facts that allow an inference that the [products] sold or offered for sale have no substantial non-infringing uses." *In re Bill of Landing Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337 (Fed. Cir. 2012). "In assessing whether a use is substantial, the fact-finder may consider 'the use's frequency, . . . the use's practicality, the invention's intended purpose, and the intended market.'" *Id.* (quoting *i4i Ltd. P'ship v. Microsoft Corp.*, 595 F.3d 831, 851 (Fed. Cir. 2010)). Importantly, substantial uses are not those that are "unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1362 (Fed. Cir. 2012) (quoting *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009)).

Here, Takeda has alleged facts that FMF treatment with generic Colcrys® will be insubstantial. Takeda's amended complaint alleges that the United States market for Colcrys® in the treatment of FMF is minuscule and in light of physician and pharmacist prescribing practices, the anticipated sales of Amneal's product to FMF patients will be insubstantial compared to the sales to gout patients. These allegations are supported by national prescription data and the declaration of Dr. Chad Boomershine, a Board Certified Rheumatologist. Thus, Takeda's Amended Complaint sufficiently alleges that, following FDA approval, there will be no substantial uses for generic Colcrys® other than its infringing use as part of a method to treat gout.

2. *Contributory infringement claims under 35 U.S.C. § 271(c) are permissible when the proposed generic label “carves out” the patented indication.*

In another Hatch-Waxman case involving a very similar set of facts, the District Court of New Jersey recognized a patentee's right to seek a declaratory judgment of infringement under § 271(c). *Novartis Pharmaceuticals Corp. v. Wockhardt USA LLC*, No. 13-cv-1028, 2013 WL 5770539, at \*10 (D.N.J. Oct. 23, 2013) (hereinafter, the “Reclast® case”). The FDA approved the drug Reclast® (zoledronic acid) to treat one indication for which it is prescribed in large volumes (osteoporosis) and another for which it is prescribed far less frequently (Paget's disease). (See Bourke Decl. ¶ 7, Ex. E [D.I. 128 [Am. Compl.] in Reclast® case, No. 13-cv-1028 (D.N.J.)] at ¶ 71.) According to Novartis's allegations, only 0.3% of Reclast® patients each year were being treated for Paget's disease, and the other 99.7% of Reclast® patients each year were being treated for a condition other than Paget's disease. (See *id.* at ¶ 72.) Novartis owns an Orange Book listed patent claiming a method of administering zoledronic acid to treat the more common osteoporosis indication. *See* Reclast® case, No. 13-cv-1028, 2013 WL 5770539 at \*1.

Similar to Amneal's tactics here, seven generic companies filed ANDAs seeking approval for generic Reclast® to treat Paget's disease, but carving out any osteoporosis indication from their proposed labels. *Id.* at \*2.

Novartis asserted patent infringement claims based on its osteoporosis patent under 35 U.S.C. §§ 271(e), (b), and (c). The court dismissed the §§ 271(e) and (b) claims on the ground that those claims could only be asserted where the generic company sought FDA approval for the patented method. *Id.* at \*7-9. Because the generic companies had carved out the osteoporosis indication from their labels, the court held that there could be no claim for direct infringement or inducement of infringement under those sections. However, Novartis had also asserted a claim

for contributory infringement under section 271(c). Novartis alleged that, irrespective of the generic label, physicians would prescribe the generic drug for the osteoporosis indication for which the brand drug was approved, thereby infringing its patents, and that the generic companies would be contributing to such infringement. Novartis further alleged that the use of the drug for Paget's disease, the indication for which the generic companies sought FDA approval, would be insignificant and not rise to the level of a substantial non-infringing use. The court refused to dismiss that claim, holding that "determining whether the disputed *non-infringing* use—treatment of Paget's disease—is 'substantial'" is a question of fact that "cannot be done at the pleadings stage." *Id.* at \*10 (citing *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 31 F. Supp. 2d 921, 924 (D. Kan. 1998).) In so holding, the court rejected defendants' argument that "an FDA approved indication is necessarily substantial." *Id.*

The court's ruling was consistent with well-established precedent that substantial noninfringing use is a factually intensive issue not appropriate for resolution at the pleadings stage. *Id.* at \*10; *accord Braintree*, 31 F. Supp. 2d at 924 (D. Kan. 1998) ("A claim of contributory infringement involves the resolution of complicated fact questions unsuitable for determination on a motion to dismiss. Indeed, whether a product is capable of being sold for a substantial noninfringing use is a question of fact, the resolution of which is more appropriately determined at the summary judgment stage, in the event that no material issues of fact exist, or at a trial on the merits."); *Imagexpo, L.L.C. v. Microsoft Corp.*, 284 F. Supp. 2d 365, 368 (E.D. Va. 2008) (denying summary judgment); *Oak Indus., Inc. v. Zenith Elecs. Corp.*, 697 F. Supp. 988, 995-96 (N.D. Ill. 1998) (denying summary judgment); *Union Carbide*, 2004 WL 1305849, at \*7 (denying judgment as a matter of law).

**V. CONCLUSION**

For the reasons stated above and in the interest of justice, Takeda respectfully requests that the Court grant Takeda leave to file its Amended Complaint and that the Amended Complaint be deemed filed and served as of the date the Court grants such relief.

WOMBLE CARLYLE SANDRIDGE & RICE, LLP

/s/Mary W. Bourke

Mary W. Bourke (#2356)  
222 Delaware Avenue, Suite 1501  
Wilmington, DE 19801  
mbourke@wCSR.com  
Phone: (302) 252-4333

OF COUNSEL:

Tryn T. Stimart  
WOMBLE CARLYLE SANDRIDGE & RICE, LLP  
8065 Leesburg Pike, 4<sup>th</sup> Floor  
Tysons Corner, VA 22182-2738  
tstimart@wCSR.com

*Attorneys for Takeda Pharmaceuticals U.S.A., Inc.*

Jeffrey I. Weinberger  
Ted G. Dane  
MUNGER, TOLLES & OLSON LLP  
355 South Grand Avenue  
Thirty-Fifth Floor  
Los Angeles, California 90071-1560  
jeffrey.weinberger@mto.com  
ted.dane@mto.com

Eric K. Chiu  
MUNGER, TOLLES & OLSON LLP  
560 Mission Street  
San Francisco, California 94105-2907  
eric.chiu@mto.com

Dated: May 30, 2014

**CERTIFICATE OF SERVICE**

I hereby certify that on May 30, 2014 I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on May 30, 2014, upon the following individuals via electronic mail:

Paul S. Tully, Ph.D.	Mary Matterer
Kevin E. Noonan	Richard K. Herrmann
Sherri L. Oslick	MORRIS JAMES LLP
McDONNELL BOEHNEN HULBERT &	500 Delaware Avenue, Suite 1500
BERGHOFF LLP	Wilmington, DE 19899
300 South Wacker Drive	mmatterer@morrisjames.com
Chicago, IL 60606	rherrmann@morrisjames.com
tully@mbhb.com	
noonan@mbhb.com	
oslick@mbhb.com	

**WOMBLE CARLYLE SANDRIDGE & RICE, LLP**

*/s/Mary W. Bourke*  
Mary W. Bourke (#2356)  
222 Delaware Avenue, Suite 1501  
Wilmington, DE 19801  
Telephone (302) 252-4320  
mbourke@wCSR.com